



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-397]

Schedules of Controlled Substances: Placement of Mesocarb in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing the substance mesocarb (chemical name: *N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle, mesocarb.

DATES: Comments must be submitted electronically or postmarked, on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference “Docket No. DEA-397” on all electronic and written correspondence, including any attachments.

- *Electronic comments:* Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the webpage or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the on-line instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <http://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been submitted successfully, and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, send via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

- *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing

Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want to make it publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want to make it publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

DEA will generally make available in publicly redacted form comments containing personal identifying information and confidential business information identified as directed above. If a comment has so much confidential business information that it cannot be effectively redacted, DEA may not make available publicly all or part of that comment. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

Request for Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and they shall include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. 21 CFR 1316.47(a). Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above.

Legal Authority

The United States is a party to the 1971 Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2) - (4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of the Department of Health and Human Services (HHS),¹ after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance. 21 U.S.C. 811(d)(3). In the event that the Secretary of HHS (Secretary) did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of DEA. 28 CFR 0.100.

Background

Mesocarb, known chemically as *N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate, has central nervous system (CNS) stimulating

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substances Act, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

properties, and it has no approved medical use in the United States. Mesocarb (Sydnocarb) is marketed in Russia as a treatment for attention deficit hyperactivity disorder. Mesocarb's primary mode of action is to stimulate the CNS via dopamine (DA) activation resulting in increased mental capacity and activity.

Pursuant to 21 U.S.C. 811(d)(2), HHS published two notices in the *Federal Register* regarding mesocarb. The first notice requested the World Health Organization (WHO) consider information in preparing its scientific and medical evaluation for mesocarb.² The second notice solicited public comment regarding a recommendation by WHO to impose international controls on mesocarb.³ At its 38th session (1995), the United Nations Commission on Narcotic Drugs (UN/CND) listed mesocarb in Schedule IV of the 1971 Convention. Specifically, based on advice from WHO, UN/CND placed mesocarb in Schedule IV due to its low to moderate dependence potential and its appreciable abuse liability. Furthermore, mesocarb was found to have both little to moderate therapeutic usefulness and a similar spectrum of pharmacological effects as other substances in Schedule IV of the 1971 Convention. The CSA, in 21 U.S.C. 812(b), sets forth findings required to place a substance in a certain schedule under the CSA. As discussed below in the Proposed Determination to Schedule Mesocarb and Proposed Determination of Appropriate Schedule sections, DEA found that mesocarb must be placed in schedule I of the CSA.

Article 2, paragraph 7(d), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule IV of the 1971 Convention. Pursuant to the 1971 Convention, the United States must require licenses for the manufacture, export and import, and distribution of

² International Drug Scheduling; Convention on Psychotropic Substances; Certain Stimulant/Hallucinogenic Drugs and Certain Nonbarbiturate Sedative Drugs, 59 FR 31639, June 20, 1994.

³ International Drug Scheduling; Convention on Psychotropic Substances; World Health Organization Scheduling Recommendations for Seven Drug Substances, 60 FR 4169, January 20, 1995.

mesocarb. The CSA's registration requirement accomplishes this license requirement, as set forth in 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. In addition, the United States must adhere to specific export and import provisions set forth in the 1971 Convention. The CSA's export and import provisions accomplish this requirement, as established in 21 U.S.C. 952, 953, 957, and 958 and in accordance with 21 CFR part 1312. Likewise, under Article 13, paragraphs 1 and 2, of the 1971 Convention, a party to the 1971 Convention may notify another party, through the Secretary-General of the United Nations, that it prohibits the importation of a substance in Schedule II, III, or IV of the 1971 Convention. If such notice is presented to the United States, the United States shall take measures to ensure that the named substance is not exported to the country of the notifying party. The CSA's export provisions mentioned above accomplish this requirement. Article 16, paragraph 4, of the 1971 Convention requires the United States to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) in regard to each Schedule I and II substance of the 1971 Convention, quantities manufactured in, exported to, and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each Schedule II and III substance of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (3) in regard to each Schedule II - IV substance of the 1971 Convention, quantities used for the manufacture of non-psychoactive substances or products. Lastly, under Article 2 of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. Persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action; therefore, the United States complies with this provision.

Proposed Determination to Schedule Mesocarb

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on mesocarb and, in 2008, submitted it to the Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for mesocarb. On April 3, 2012, HHS provided to DEA a written scientific and medical evaluation and scheduling recommendation entitled “Basis for the Recommendation for Control of Mesocarb in Schedule I of the Controlled Substances Act (CSA).” Pursuant to 21 U.S.C. 811(b), this document contained HHS’ eight-factor analysis of the abuse potential of mesocarb, along with its recommendation that mesocarb be added to schedule I of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS and all other relevant data and conducted its own eight-factor analysis of mesocarb’s abuse potential pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in its proposed scheduling determination. Please note that both DEA and HHS analyses are available in their entirety under “Supporting Documents” of the public docket for this rule at <http://www.regulations.gov> under docket number “DEA-397.”

1. *The Drug’s Actual or Relative Potential for Abuse:* As reported by HHS, DA is known to increase locomotion and is also directly involved in the rewarding, stimulatory, and antidepressant effects induced by psychostimulants. Mesocarb, known to be a selective inhibitor of the DA transporter, is readily self-administered at levels equal to that of methamphetamine in animals, demonstrating the reinforcing effects of mesocarb. Clinical studies have also confirmed the reinforcing effect of mesocarb as compared to both amphetamine and methamphetamine, both of which are schedule II drugs. While reports of mesocarb abuse are rare, anti-doping tests have led to the

detection of unauthorized use of the drug by athletes during training and competition. Effects following administration of mesocarb include increased locomotion, increased work capacity, improved cardiovascular function, a marked psychostimulant effect, excessive vitality or nervous energy, tachycardia, hypertension, weight loss, and decreased appetite. These data indicate that mesocarb has the potential for abuse similar to other CNS stimulants.

2. Scientific Evidence of the Drug's Pharmacological Effects, If Known:

Mesocarb modulates the uptake of DA, norepinephrine and 5-hydroxytryptamine, all of which are directly involved in the rewarding, stimulatory, and antidepressant effects induced by these psychostimulants. In comparison to amphetamine, mesocarb has a slower onset of action and is less potent; however, the stimulant effects of mesocarb on the CNS are longer lasting. Mesocarb is readily self-administered in both mice and monkeys and is shown to substitute fully for both amphetamine and methamphetamine when tested in a discriminative paradigm. Self-administration findings have also predicted that mesocarb has abuse potential, even though it is approximately ten times less potent than methamphetamine.

Mesocarb use in the United States is rare, and clinical information pertaining to its abuse potential is limited. Mesocarb is not studied scientifically outside of Russia or other countries that made up the former Union of Soviet Socialist Republics (USSR). In a clinical review by the Institute of Psychiatry of the Academy of Medical Sciences USSR and the Institute of Psychiatry of the Ministry of Health (Moscow), mesocarb was reported to produce a marked psychostimulant effect characterized by increased mental and physical activity along with increased locomotor and speech activity. Clinical observations demonstrate that mesocarb, while less potent than both methamphetamine and amphetamine, has similar CNS effects as other stimulants, providing evidence that mesocarb has a similar abuse liability.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other*

Substance: Mesocarb is a white crystalline powder, nearly insoluble in water and barely soluble in alcohol. Of the 19 reported metabolites of mesocarb, the main metabolite is *p*-hydroxymesocarb (conjugated with sulfate), which is detected in human urine and plasma. Amphetamine in trace amounts has also been detected as a metabolite of mesocarb (in human urine and blood plasma, and in rat urine). In healthy human volunteers, the estimated detection time for mesocarb after administration was approximately 10–11 days, due to the long half-lives of the metabolites.

4. *Its History and Current Pattern of Abuse:* Abused by athletes worldwide both in training and in competition, mesocarb is on the list of prohibited substances of the World Anti-Doping Agency (WADA) and banned by the International Olympics Committee. In addition, mesocarb is internationally controlled as a Schedule IV substance under the 1971 Convention. Diversion of legitimately produced mesocarb in Bulgaria was mentioned as a possible problem in the International Narcotics Control Strategy Report (INCSR) of 1993. In 2000, INCSR reported the primary stimulant of abuse, amphetamine, was being replaced by fenethylline (schedule I of the CSA), pemoline (schedule IV of the CSA), mesocarb, and ephedrine (in that order) in western Africa. Queries of DEA's System to Retrieve Information from Drug Evidence (STRIDE)/STARLiMS⁴ and the National Forensic Laboratory Information System (NFLIS)⁵ on May 26, 2021, did not report any occurrence of mesocarb, suggesting that mesocarb is not trafficked in the United States.

⁴ STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from DEA, other federal agencies, and law enforcement agencies. On October 1, 2014, STARLiMS replaced STRIDE as DEA laboratory drug evidence data system of record.

⁵ NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country. The NFLIS participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is over 97%. NFLIS includes drug chemistry results from completed analyses only.

5. *The Scope, Duration, and Significance of Abuse:* As noted above, mesocarb is prohibited by WADA and banned by the International Olympic Committee. It has been used by athletes worldwide both in training and in competition due to reported effects on learning, memory, work capacity, and antihypoxia. Case reports involving mesocarb abuse have included: (1) a Lithuanian athlete in the Barcelona 1992 Olympic games; (2) a U.S. citizen in the Tokyo 1991 International Amateur Federation World Championships; (3) a Bulgarian athlete in the Helsinki 1994 European Championships; (4) a report by observers for WADA covering the Mediterranean Games of Tunis (Tunisia) in 2001; and (5) another WADA report in 2005 following a positive laboratory result that tested positive for mesocarb.

6. *What, if any, Risk There is to the Public Health:* The presence of mesocarb in the United States is limited because of its lack of accepted medical use. According to HHS, mesocarb is not an approved drug, and there have been no reports of adverse effects related to mesocarb in the United States. Due to the pharmacological similarity of mesocarb to amphetamine and methamphetamine, even though the availability of mesocarb is limited, mesocarb likely presents similar risks to the public health as amphetamine and methamphetamine.

7. *Its Psychic or Physiological Dependence Liability:* For amphetamine or amphetamine-like substances, related withdrawal symptoms can be moderate or limited and are characterized by craving, irritability, nervousness, psychomotor agitation, paranoia, and sleep disturbances. Although there are no direct assessments of the physiologic and psychic dependence of mesocarb, it does induce locomotor and self-administration behaviors that are similar to those behaviors induced by amphetamine and methamphetamine. Mesocarb has been shown to substitute fully at high doses to amphetamine and methamphetamine in a drug discriminative paradigm. Therefore,

mesocarb likely elicits a similar physiologic and psychic dependence profile as amphetamine and methamphetamine.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* Both HHS and DEA find that mesocarb is not an immediate precursor of any substance already controlled under the CSA.

Conclusion: Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of mesocarb. As such, DEA hereby proposes to schedule mesocarb as a controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) Mesocarb has a high potential for abuse. Mesocarb, similar to amphetamine and many other CNS stimulants, is a DA uptake inhibitor. In clinical observations, mesocarb produced marked psychostimulation accompanied with increased mental, physical, locomotor, and speech activity similar to amphetamine, albeit with less potency. Pre-clinical research has also directly compared mesocarb to other CNS stimulants, including amphetamine and methamphetamine that are scheduled and controlled under the CSA due to their well-known high abuse liability. The effects of mesocarb on DA are qualitatively similar to these schedule II stimulants. Intravenous drug self-administration studies in animals have shown that mesocarb has reinforcing effects. Mesocarb shares similar discriminative stimulus effects with amphetamine and methamphetamine, though

at larger doses. Amphetamine and methamphetamine have medical use and have high potential for abuse.

(2) There are no approved New Drug Applications for mesocarb nor is there a known therapeutic application for mesocarb in the United States. Therefore, mesocarb has no currently accepted medical use in treatment in the United States.⁶

(3) There is a lack of accepted safety for use of mesocarb under medical supervision since mesocarb lacks any accepted medical use in the United States. Clinical findings demonstrate that mesocarb induces similar effects characteristic of other CNS stimulants including amphetamine and methamphetamine. Adverse effects reported for mesocarb include tachycardia, hypertension, weight loss, and decreased appetite.

Based on these findings, the Administrator of DEA concludes that mesocarb warrants control under schedule I of the CSA. 21 U.S.C. 812(b)(1). More precisely, because of its stimulant effects, DEA proposes placing mesocarb in 21 CFR 1308.11(f) (the stimulants category of schedule I). As such, the proposed control of mesocarb includes the substance as well as its salts, isomers, and salts of isomers.

Requirements for Handling Mesocarb

If this rule is finalized as proposed, mesocarb would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

⁶ Although there is no evidence suggesting that mesocarb has currently accepted medical uses in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) mesocarb, or who desires to handle mesocarb, would need to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312 as of the effective date of a final scheduling action. Any person who currently handles mesocarb and is not registered with DEA would need to submit an application for registration and may not continue to handle mesocarb as of the effective date of a final scheduling action, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration would be required to surrender all quantities of currently held mesocarb or transfer all quantities of currently held mesocarb to a person registered with DEA before the effective date of a final scheduling action in accordance with all applicable federal, State, local, and tribal laws. As of the effective date of a final scheduling action, mesocarb would be required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Mesocarb would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of a final scheduling action. Non-practitioners handling mesocarb would also need to comply with the employee screening requirements of 21 CFR 1301.90 -1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of mesocarb would need to be in compliance with 21 U.S.C. 825 and 958(e) and in accordance with 21 CFR part 1302, as of the effective date of a final scheduling action.

5. *Quota.* Only registered manufacturers would be permitted to manufacture mesocarb in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of the effective date of a final scheduling action.

6. *Inventory.* Every DEA registrant who possesses any quantity of mesocarb on the effective date of a final scheduling action would be required to take an inventory of mesocarb on hand at that time, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who becomes registered with DEA on or after the effective date of the final scheduling action would be required to take an initial inventory of all stocks of controlled substances (including mesocarb) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant would be required to take a new inventory of all controlled substances (including mesocarb) on hand every two years, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports for mesocarb, or products containing mesocarb, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317, as of the effective date of a final scheduling action. Manufacturers and distributors would be required to submit reports regarding mesocarb to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of the effective date of a final scheduling action.

8. *Order Forms.* Every DEA registrant who distributes mesocarb would be required to comply with order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305, as of the effective date of a final scheduling action.

9. *Importation and Exportation.* All importation and exportation of mesocarb would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958 and in accordance with 21 CFR part 1312 as of the effective date of a final scheduling action.

10. *Liability.* Any activity involving mesocarb not authorized by, or in violation of, the CSA or its implementing regulations, would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to Section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601-612, has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA proposes placing the substance mesocarb, including its isomers, salts, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle, mesocarb.

According to HHS, mesocarb has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use

under medical supervision. DEA's research confirms that there is no commercial market for mesocarb in the United States. Additionally, queries of DEA's STRIDE/STARLiMS and the NFLIS databases on May 26, 2021, did not generate any reports of mesocarb, suggesting that it is not trafficked in the United States. Therefore, DEA estimates that no United States entity currently handles mesocarb and does not expect any United States entity to handle mesocarb in the foreseeable future. DEA concludes that no United States entity would be affected by this rule if finalized. As such, the proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of \$100,000,000 or more (adjusted annually for inflation) in any 1 year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308— SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. Section 1308.11 is amended by redesignating paragraphs (f)(7) through (10) as paragraphs (f)(8) through (11), and adding a new paragraph (f)(7) to read as follows:

§ 1308.11 Schedule I.

* * * *

(f) * *

(7) Mesocarb (*N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimide)..... 1227

* * * *

(f) *Stimulants*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Aminorex (Some other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenyl-2-oxazolamine)	1585
(2) N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine)	7493
(3) Cathinone	1235
Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone	
(4) Fenethylamine	1503
(5) Methcathinone (Some other names: 2-(methylamino)-propionophenone; alpha-(methylamino)propionophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha- <i>N</i> -methylaminopropionophenone; monomethylpropion; ephedrone; <i>N</i> -methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR1432), its salts, optical isomers and salts of optical isomers	1237
(6) (±) <i>cis</i> -4-methylaminorex ((±) <i>cis</i> -4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine)	1590
(7) N-ethylamphetamine	1475
(8) <i>N,N</i> -dimethylamphetamine (also known as <i>N,N</i> -alpha-trimethylbenzeneethanamine; <i>N,N</i> -alpha-trimethylphenethylamine)	

Anne Milgram,

Administrator.

[FR Doc. 2021-16489 Filed: 8/10/2021 8:45 am; Publication Date: 8/11/2021]